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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/551,977 04/14/00 POLO

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Intellectual Property - R440
P.O. Box 8097
Emeryville CA 96662-8097

EXAMINER

| ART UNIT | PAPER NUMBER |
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I.T.B
1648
DATE MAILED:

05/30/01

TP

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/551,977 | POLO ET AL. |
| | Examiner Bao Qun Li | Art Unit 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 05, 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s). _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____.

DETAILED ACTION***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-6, drawn to an isolated alphavirus ATCC NO. VR-2643, classified in class 435, subclass 235.1
- II. Claims 7-10, drawn to a nucleic acid molecule encoding an alphavirus, classified in class 536, subclass 23.72.

If Group II is elected, further elect one of the following a nucleic acid molecule is required under 35 U.S.C. 121:

- (1). A nucleic acid molecule encoding an alphavirus encoded by a sequence shown on Fig 2B
- (2). A nucleic acid molecule encoding an alphavirus encoded by a sequence shown in Figure 2C.
- III. Claims 11 and 13-14, drawn to an alphavirus packaging cell line that transfected with a viral vector that expresses a alphavirus structure protein, classified in class 435, subclass 346.
- IV. Claims 12 and 13-16, drawn to an alphavirus packaging cell line that transfected with a viral vector that expresses a mutated alphavirus structure protein, classified in class 424, subclass 363.
- V. Claims 17, 19-23, drawn to a recombinant Sindibit virus, classified in class 424, subclass 218.1.
- VI. Claims 18 and 20-22, drawn to a recombinant Semiliki Forest virus, classified in class 424, subclass 202.1.
- VII. Claims 24-34, drawn to a method for introducing a heterologous sequence into a cell, classified in class 435, subclass 362.
- VIII. Claim 35, drawn to an alphavirus vector construct, classified in class 435, subclass 320.1.
- IX. Claim 36, drawn to an eukaryotic layered vector, classified in class 435, subclass 91.41.

X. Claim 37, drawn to an alphavirus RNA vector replicon, classified in class 435, subclass 91.51.

Inventions of Groups I-VI and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups of invention are directed to structurally different products and they produce different biological effects, e.g. the cell line of the Group III can be used to produce protein, whereas the product of either Group I can be used for induce immune response.

Inventions Group (1) and (2) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the virus in Group (1) differs from the virus in Group (2) in that they are encoded by different nucleic acid sequences, and different nucleic acid sequence is translated into different protein. Consequently, they produce different immune responses when they are used to immunize the animal.

Inventions VII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and material different process, such as purification from insect cell that is transformed with a vector carrying the recombinant virus.

Because these inventions are distinct for the reasons given above and have acquired a separate status, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Application/Control Number: 09/551,977 Page 4
application. Any amendment of inventorship must be accompanied by a petition under 37
CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

April 6, 2001

James C. Housel
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
5/28/01